DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2005

Ms. Cindy Domecus
Vice President
Clinical Research and Regulatory Affairs
Kyphon Inc.
1221 Crossman Avenue
Sunnyvale, California 94089

Re: K041454
Trade/Device Name: KyphX® Inflatable Bone Tamps
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: May 28, 2004
Received: June 1, 2004

Dear Ms. Domecus:

This letter corrects our substantially equivalent letter of July 9, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

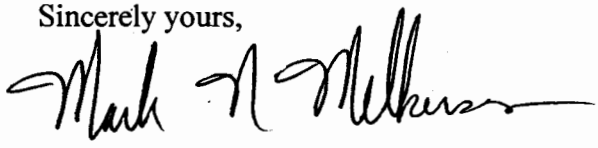
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K041454

Device Name: KyphX® Inflatable Bone Tamps

Indications for Use:

KyphX® Inflatable Bone Tamps are intended to be used as conventional bone tamps for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with KyphX® HV-R™ Bone Cement), hand, tibia, radius and calcaneus.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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510(k) Number K041454

K041454

Premarket Notification [510(k)] Summary

May 28, 2004

JUL 0 9 2004

Trade Name:	Kyphx® Inflatable Bone Tamps
Common Name:	Inflatable Bone Tamp
Classification Name:	Tamp (per 21 CFR section 888.4540) and Arthroscope (per 21 CFR section 888.1100)
Manufacturer's Name: Address:	Kyphon Inc. 1221 Crossman Avenue Sunnyvale, CA 94089 (408) 548-6500
Contact Person:	Cindy Domecus Vice President, Clinical Research & Regulatory Affairs
Predicate Device(s):	KyphX® Directional Inflatable Bone Tamp, K032212 KyphX® Inflatable Bone Tamp, K010246 Kyphon Inflatable Bone Tamp, K981251
Device Description:	The KyphX® Inflatable Bone Tamps are the identified predicate devices. They are bone tamps with an inflatable component at the distal end. The products have the same technological characteristics and intended use as described for the predicates. Safety and effectiveness for use in kyphoplasty procedures is described in K033801.
Indication for Use:	KyphX® Inflatable Bone Tamps are intended to be used as conventional bone tamps for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with KyphX® HV-R™ Bone Cement), hand, tibia, radius and calcaneus.

As with Kyphon's cleared Kyphon and KyphX® Inflatable Bone Tamp 510(k)s, K981251, K102046, and K032212, and Kyphon's cleared KyphX® HV-R™ Bone Cement 510(k), K033801, any statement regarding "substantial equivalence" made in this submission only relates to whether the product addressed in this submission may be lawfully marketed without premarket approval or reclassification, and is not intended to be interpreted as an admission or any other type of evidence in any patent proceeding, including patent infringement litigation or proceeding before any Patent Office. The present submission and statements therein therefore should not be construed as affecting or relating to the scope of any patent or patent application, or to whether the product addressed in this submission, or its use, may be considered indistinct, from a patentability perspective, from any of the other devices referenced in this filing.